

California Drug Safety Notification



Notification Name

U. S. FDA Requires Fluoroquinolone Antibacterial Drug Label Update to Warn of Risk of Permanent Nerve Injury

Notification Date	Notification Details	Notification Recommendation
08/15/13	The U.S. Food and Drug Administration (FDA) has required drug labels and Medication Guides for Levaquin (levofloxacin), Cipro (ciprofloxacin), and other fluoroquinolone antibacterial drugs to be updated with a better description of the potential serious side effect of peripheral neuropathy. The risk is associated with fluoroquinolones taken by mouth or injection only. It is not known to be associated with the topical formulation.	Patients should receive a Medication Guide and be advised to contact their health care professional right away if symptoms of peripheral neuropathy develop. Symptomatic patients should be evaluated and potentially switched to a non-fluoroquinolone antibacterial drug.

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

http://www.fda.gov/Drugs/DrugSafety/ucm365050.htm